Alternative Design 3 Report

MEDSense: A Portable Pill Dispensing Device

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I. Introduction

Today, modern pharmacological establishments spend billions of dollars each year on advertising due to the exponentially growing supply of competing prescription medications. Patients now find themselves in a world where dangerous conditions and diseases are easily managed by relatively affordable medications. Although a remarkable increase in life expectancy of the American population over the past fifty years could additionally be attributed to an increased awareness of daily health issues, it could easily be argued that the primary culprit is the ubiquity of pharmaceutical products. As the number of available medications increases, however, patients are finding themselves reliant on a growing number of daily medications. Ultimately, many individuals accumulate an unmanageable number of medications, a problem that could potentially lead to unintentional neglect of prescribed schedules and dosages.

This proposal outlines the development and production of a pill cap designed to dispense and cut medication for persons with disabilities. This project is being done for the Rehabilitation Engineering Research Center on Accessible Medical Instrumentation (RERC on AMI) competition headed by Dr. John Enderle. The driving goal in designing this device is to provide a means for persons with disabilities to access vital medication when traditional pill caps prove to be increasingly difficult. Certain difficulties associated with the prospective clients' disabilities will be discussed later in the proposal. Also, more specific requirements relating to the programming and mechanical performance of the project will be outlined.

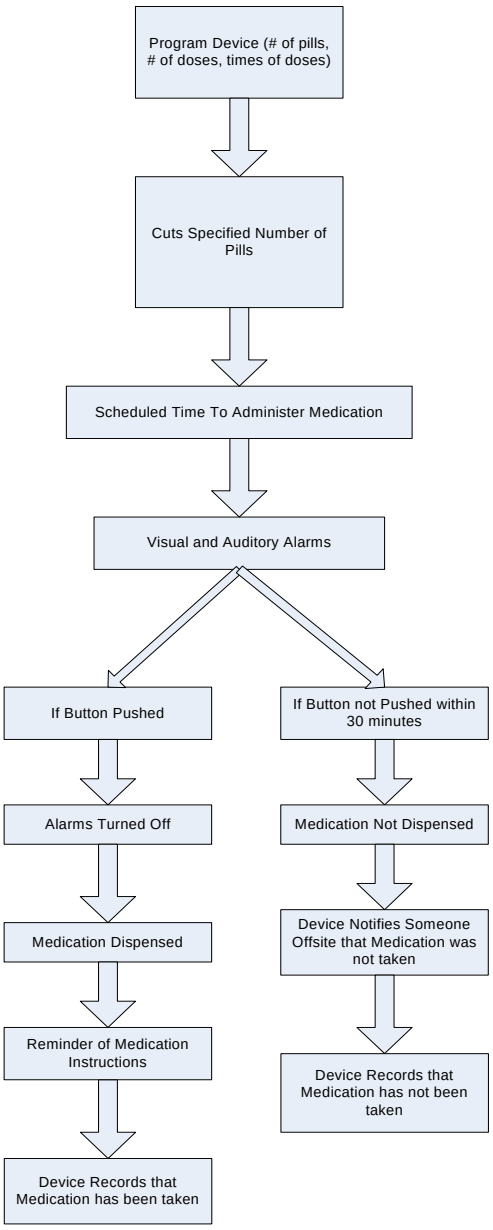

Program Device (# of pills, # of doses, times of doses)
Cuts Specified Number of Pills
Scheduled Time To Administer Medication
Visual and Auditory Alarms
If Button Pushed
If Button not Pushed within 30 minutes
Alarms Turned Off
Medication Not Dispensed
Medication Dispensed
Device Notifies Someone Offsite that Medication was not taken
Reminder of Medication Instructions
Device Records that Medication has not been taken
Device Records that Medication has been taken

Fig 1. Device Flow Chart

This product is an accessible pill cap that dispenses the correct amount of medication at a set time for elderly patients or patients with disabilities. It is difficult for some patients to remember when to take their medication, as well as how much medication to take. It may also be a problem for the patient to cut a pill in half if a half dosage is prescribed. The diverse disabilities of the patients for whom we are designing this pill cap include vision loss due to macular degeneration, hearing loss, loss of or decreased strength and motion in one hand or arm, memory loss and Dementia. Some minor problems that affect these patients that must be kept in mind while designing this pill cap are being in a wheelchair,

loss of legs, neuropathy in the hands, hand tremors, having small children and being easily intimidated by high-tech machines.

The main features of this product are designed to aid the patients in their medication routine. The multi-modal alert system lets patients know when it is time to take their medication with both visual and auditory alarms for patients with hearing loss or vision loss. The automated cutting mechanism accurately cuts pills in half if a half dose is required for patients with macular degeneration or a missing limb. The reminder to order a new prescription when the old prescription runs out is designed for elderly patients, patients with Dementia or memory loss, or busy patients who don't have a lot of time to think about their medication. The offsite alert system, which notifies a family member, nurse or doctor offsite if a dose is missed by the patient, is a built in safety device so a responsible party is notified if something happens to the patient and they miss their dose. An easy-to-use interface is needed since many elderly persons are intimidated by technology and so the device is simple and user-friendly.

Other features that are not required but that will add to the accessibility of the product will be implemented. Patient safety is a huge concern for the project plan, so the designers of the device will put the patient's safety as their number one priority while designing the pill dispenser. A security device should be installed to ensure that third-party members do not tamper with the schedules or amount of dosage programmed into the pill dispenser since this could seriously harm the patient if an incorrect dose is taken. This device should also be waterproof since many medications are taken with water. Water can cause electrical damage and malfunctioning of electrical equipment. A major safety concern for this product is that it is childproof. Children often mistake medicine pills as candy and will unknowingly consume pills that are left lying in a tray. Therefore, it is important that this design ensures the safety not only of the user, but also of any unsuspecting third party members.

This design has significant changes in relation to the first two submitted designs. One major change is that the blade will be moving horizontally instead of vertically. In the previous design the linear actuator was either pushing a piston or a blade downward. Another major change is the overall simplicity of this design. The storage, stabilization and cutting of pills are all done in close proximity. The use of a sensor will allow the device to sense whether a pill is in the proper cutting position. If the pill is not in the proper cutting position, a problem seen in previous designs, the device will prompt the user to shake the device to prevent jamming within the funnel. This requires only gross motor skills and should not be a problem for those persons with motor difficulties. This new, simpler design will also solve problems of pill stability during cutting. The funnel will stabilize the top half of the pill while allowing the blade to cut through. Disposability was also changed in this device. The electronic elements will be able to be saved and returned to the pharmacy while the mechanical part of the device will be disposed of. The mechanical devices will be particular to one pill shape and size but many different, separate mechanical parts can be manufactured to accommodate all pill shapes and sizes. This will allow the pharmacist to attach a new mechanical part to the

electronic part for each separate prescription while saving the expensive, electronic parts for continued use.

II. Subunits

i. Dimensions

The second design concept for the device is to use two compartments; one area will consist of the cutting and dispensing of the pill and the other area will be where the notification and alert systems are housed. The rectangular design of this unit will ease the user when gripping the device. The medication bottle will be placed on top of the device on the side of the cutting and dispensing area. The use of two compartments to hold the necessary equipment will ease in the replacement of new medication, because the user will only need to bring the cutting and dispensing area back to the pharmacist. The use of a wider shape will ensure that the user has a firm grip on the device while in operation. It is critical that the device be placed on a hard surface with good support so that the mechanisms that are cutting the pill do not cut a different size. The size of the device will have a maximum dimension of 6 cm by 12 cm by 6 cm to ensure easy portability and to act as a bottle cap. An average medication bottle is about 6.35 cm in height by 2.5 cm in width with a diameter no larger than 2.54 cm. To make the device

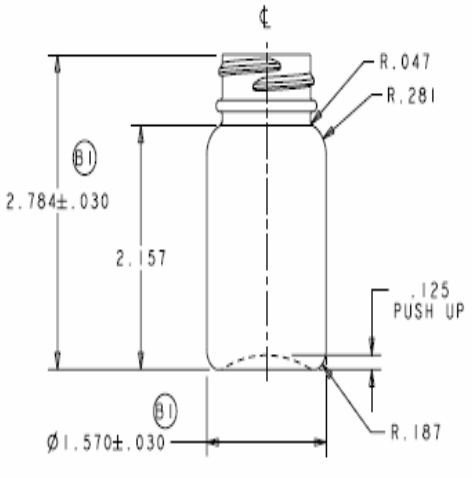


Figure 2. Medication Bottle

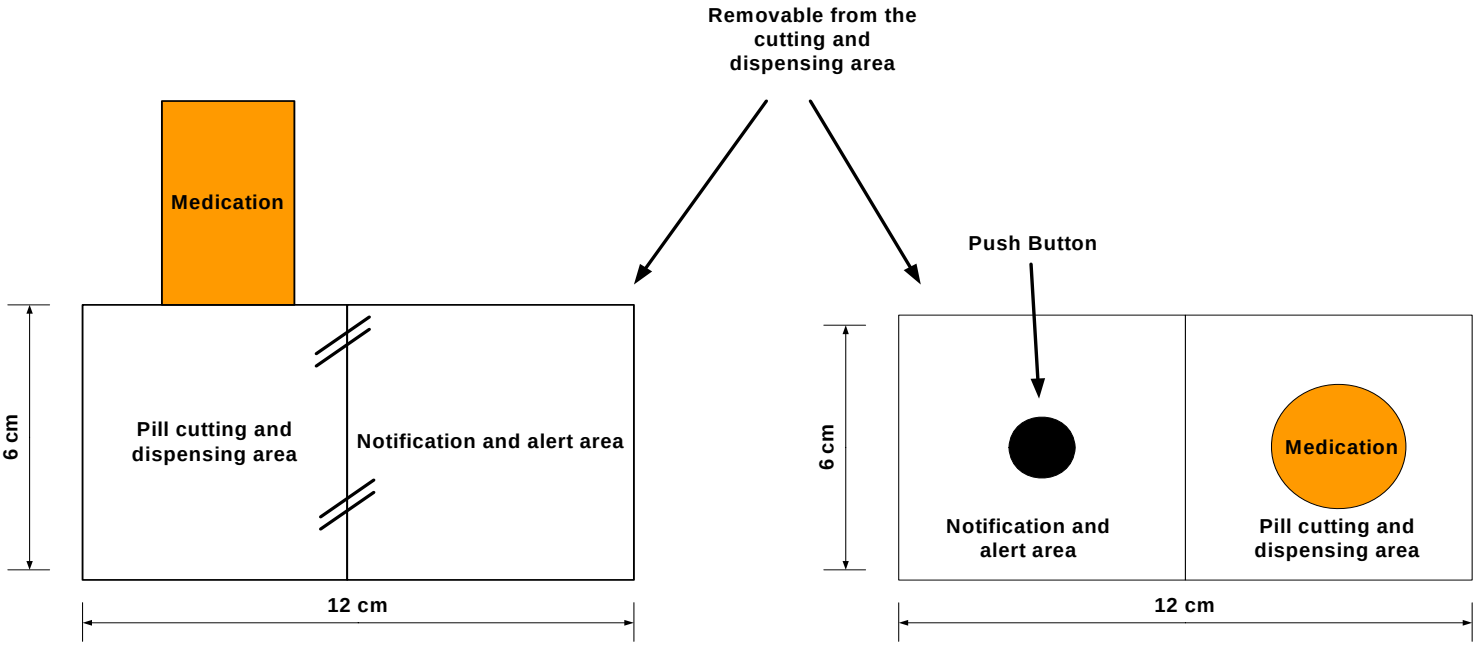


Figure 3. Top and Side View of Design 2

aesthetically pleasing, these size constraints were implemented. The ability to return half of the device to the pharmacist greatly increases the convenience of this device. This also alleviates a bulk of the device so the pharmacist and user do not have to carry around any extra weight then necessary. To cut the pill in half there will be a motor with a linear actuator; this motor will be no larger than 22 mm. Within the center of the linear actuator there will be a blade that will accurately slice the pill in half. The blade will be non-toxic, non-corrosive, and inert to all forms of medication. Single-edge blades are 0.023 cm thick and are 2.54cm in height by 1.27 cm in width. Because of the size constraints the normal blade will have to be modified to a smaller dimension. For the blade itself, stainless steel has been chosen because of its great mechanical properties; these include large tensile and compressive forces and good hardness properties. Also stainless steel is a very bioinert material thus not reacting to any of the medication.

Figure 4. Razor which will be used for cutting the medication

Once the pill bottle has been attached to the device, the pills will then travel through a cone shape into the pill holder. This will consist of a hole just larger then the actual width of the pill; this will help stabilize the pill to be cut. The pill will land on the second sliding doors so that the pill can not pass through to the exit. The dimensions of this section can not exceed 6 cm in width. The pill will be detected by an LED light to ensure that the pill has fallen correctly into the position. Once the pill has been detected a "ready" light on the outside of the device will illuminate. If jamming occurs this indicator light will notify the user and the user will then need to invert the device and slowly bring it back into position so pills can fall into the chute. A full layout of this device can be seen in Fig. 5. This device needs to have a chute just large enough to hold a single pill so that no other pills will be able to fall into the chute. The material used for the funnel and the chute will be the polyether plastic that is the same material used for the outside casing.

The notification and alert systems area will be able to be removed from the cutting and dispensing area of the device. In this area will hold the power source, PCB board, and the microchips for the LabVIEW program and the alerts. This part will also be able to be recharged when it is disconnected from the other half. The material used for this part will consist of the same plastic casting as the cutting and dispensing half; this will allow for this part to be waterproof, durable and capable of resisting moderate heat. The dimensions of this side will be 6 cm by 6cm.

For the exterior of the cutting and dispensing part, a plastic casing will be used. Plastic will be a lightweight comparison to some other materials such as aluminum. Because

this device will contain important materials, the casing needs to be durable and waterproof. Both of these requirements are satisfied by using a plastic casing. A Polyether Polyol and Polymeric plastic mixture will be used because of its low cost, high strength and resistance to heat. Plastic can be molded into many shapes and sizes, so this also helps with design an efficient and cost effective device. On the exterior of the device there will be, an activating button which will be large enough of the user to see, a "ready" light to alert the user when the pill has fallen correctly into the position, an exit window for when the pills are dispensed, and an opening to place the cap-less medicine bottle. The exterior will have a port were the medicine bottle will be placed. The operation of the device for the pharmacist will be as follows: 1. removing the cap of the user's medicine bottle, 2. inverting the entire device and placing it over the bottle and securing it as one would with a regular medicine bottle cap, 3. invert the now connected bottle and set the device upright on a hard surface (note: the original medicine bottle will be upside down), 4. pushing the "button" to activate the system once the jamming light has gone off.

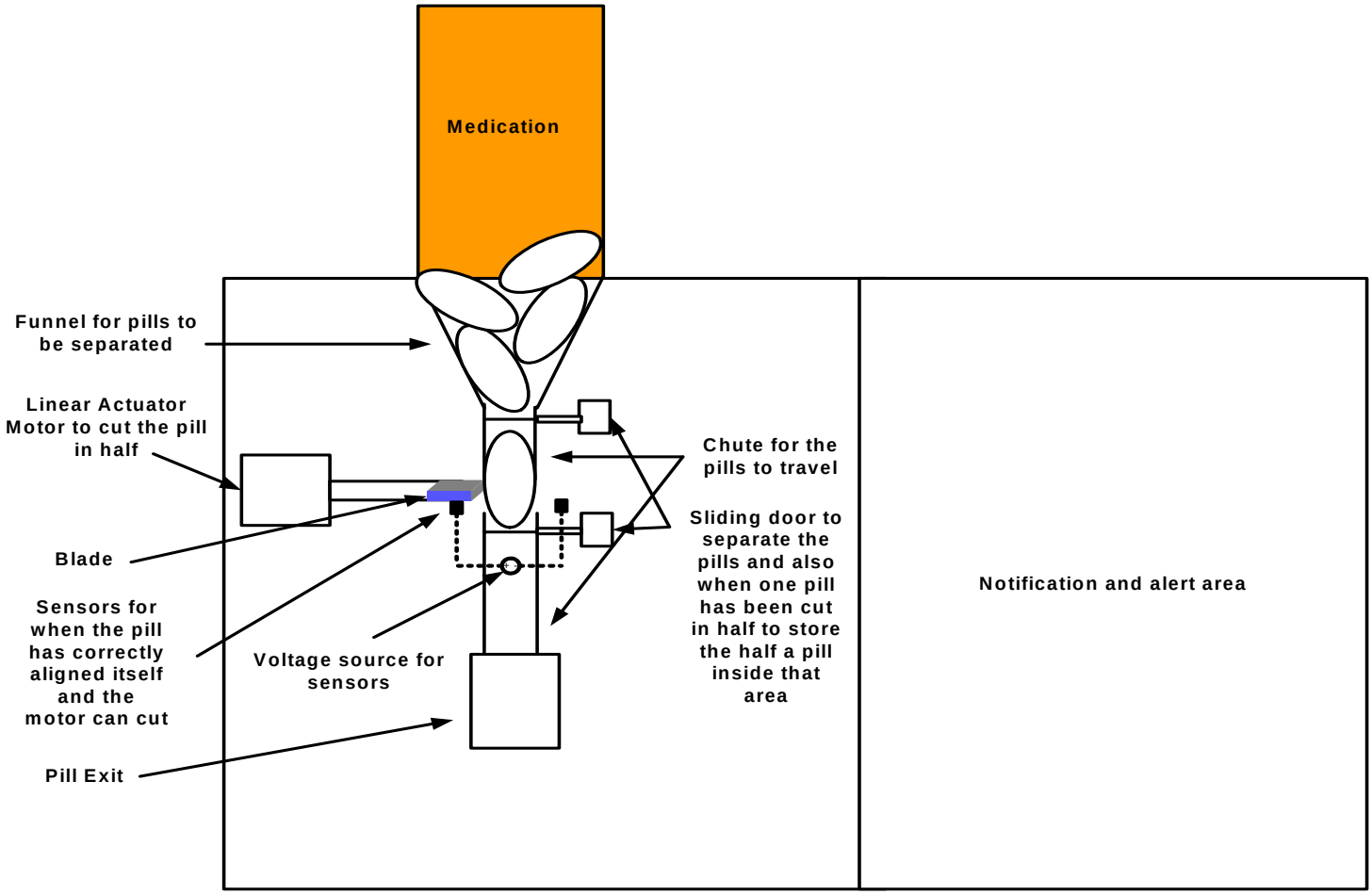

Medication
Funnel for pills to be separated
Linear Actuator Motor to cut the pill in half
Blade
Sensors for when the pill has correctly aligned itself and the motor can cut
Pill Exit
Voltage source for sensors
Chute for the pills to travel
Sliding door to separate the pills and also when one pill has been cut in half to store the half a pill inside that area
Notification and alert area

Figure 5. Specific View of Design

ii. Cutting Mechanism

The MEDSense Pill Dispenser is a pill cap that is capable of automatically cutting a pill in half. The device should be compatible with a number of pill sizes and shapes since there are a great variety of pill sizes available on the market. The following table, Table 1, shows the variety of pill sizes and shapes. [1]

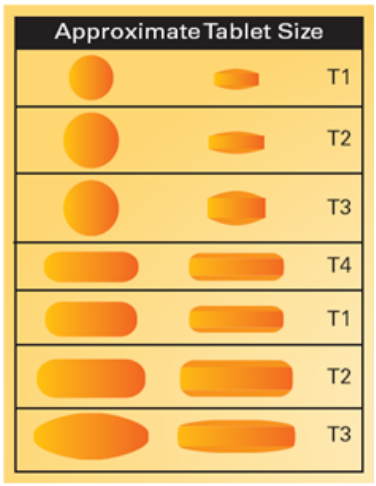


Table 1. Tablet Sizes and Shapes.

The only kind of medication that is prescribed in the half-dose is the tablet. A tablet is a carefully measured dosage of powdered drug that is tightly compressed into tablets. Tablets are usually coated by press-coating, sugar-coating or film-coating to make them smoother and easier to swallow. Some tablets, such as extended release tablets, have layers of different drugs. The outer drugs will dissolve faster and release the medication into the body, while the inner layers remain inert until they are dissolved in the stomach. However, it is very rare that extended release tablets be cut. A halved tablet's center is exposed to the stomach, therefore causing the center layers to be dissolved at the same time as the outer layers. Cutting a time-release tablet "short-circuits" the medicine, and is undesirable. Therefore, the only kind of tablet we will be focusing on is the homogeneous tablet, which may or may not have a coating.

In order to design an accurate cutting device that will split these tablets, the mechanical properties of the materials used in the tablets should be known. The strength of a compressed tablet depends on many different factors, including compression force and particle size. The following figure, Figure 6, shows the relationship between compression force, fracture resistance and hardness. [2]

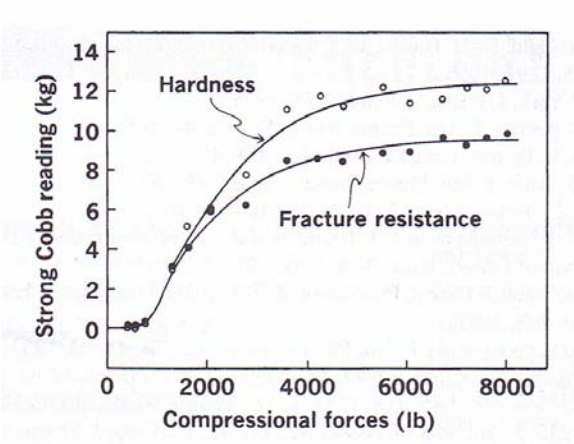


Figure 6. Compression Forces vs. Hardness and Fracture Resistance

The Strong Cobb reading is a measurement of the hardness of a tablet, which is really the compression strength of a tablet. Strong Cobb measurements are used to test the compression strength since compressed tablets are usually brittle materials, and a regular hardness test used for other materials, such as the Vickers Hardness Test, are not suitable for measuring the hardness of a compressed tablet. [3] This figure shows that as the compression forces of the tablet increase, the hardness and fracture resistance of the tablet also increase.

Another way to test for compressibility in tablets is using the Gurnham equation. This equation calculates the compressibility of pharmaceutical powders. The more compressed a powder is into a tablet, the denser it is, which, in most cases, increases its shear strength. The Gurnham equation is:

$$\varepsilon = -c\ln(P) + d \qquad \text{[Eq. 1]}$$

In this case, ε is porosity, P is pressure and c and d are constants. The porosity is related to density by this equation:

$$\varepsilon = 1 - \left(\frac{D}{D_{true}}\right) \qquad \text{[Eq. 2]}$$

In this equation, D is density and D_{true} is the true density of the powder. [4] The true densities of many solids commonly used in pharmacy can be seen in Table 2 below. [2]

TRUE DENSITY IN g/cm³ OF SOLIDS COMMONLY USED IN PHARMACY			
Aluminum oxide	4.0	Mercuric chloride	5.44
Benzoic acid	1.3	Mercuric iodide	6.3
Bismuth subcarbonate	6.86	Mercuric oxide	11.1
Bismuth subnitrate	4.9	Mercurous chloride	7.15
Bromoform	2.9	Paraffin	0.90
Calcium carbonate (calcite)	2.72	Potassium bromide	2.75
Calcium oxide	3.3	Potassium carbonate	2.29
Chalk	1.8–2.6	Potassium chloride	1.98
Charcoal (air free)	2.1–2.3	Potassium iodide	3.13
Clay	1.8–2.6	Sand, fine dry	1.5
Cork	0.24	Silver iodide	5.67
Cotton	1.47	Silver nitrate	4.35
Gamboge	1.19	Sodium borate, borax	1.73
Gelatin	1.27	Sodium bromide	3.2
Glass beads	2.5	Sodium chloride	2.16
Graphite	2.3–2.7	Sucrose	1.6
Kaolin	2.2–2.5	Sulfadiazine	1.50
Magnesium carbonate	3.04	Sulfur, precipitated	2.0
Magnesium oxide	3.65	Talc	2.6–2.8
Magnesium sulfate	1.68	Zinc oxide (hexagonal)	5.59

Table 2. True Density of Solids Commonly Used in Pharmacy

The main mechanical property that affects the cutting of a tablet in half is the shear stress. Shear stress is a stress that is parallel to the face of the material and would be exerted on the tablet by the blade cutting it in half. Shear stress can be measured by the following equation:

$$\tau = \frac{VQ}{It} \qquad \text{[Eq. 3]}$$

In the above equation, τ is the shear stress, V is the shear force, Q is the first moment of area, I is the second moment of area of the cross section and t is the thickness of the material perpendicular to shear. The force required to cause a tablet to shear will be tested using a Tinius Olsen machine.

In order to have the MEDSense device cut the tablet as accurately as possible, the stress put on the tablet should be almost all shear stress. If any other stresses are present, the tablet could fracture in other places and crumble. In order to do this, the blade will have to be very sharp and be made of an appropriate material, such as steel, to ensure that it can cut through the tablets.

A thin steel blade will be strong enough to provide the correct amount of force required to cut the tablets in half. The tablet will be held in a compartment and a steel blade will be used to cut the tablet. A linear actuator motor will provide the force necessary to accurately cut the pill in half. Stainless steel is chosen for the material because it is a strong metal and non-corrosive. The properties of stainless steel can be seen in Table 3 below. [5]

Material	Density kg/m^3	Ultimate Strength, Tension MPa	Yield Strength, Tension MPa	Yield Strength, Shear MPa	Modulus of Elasticity GPa	Modulus of Rigidity GPa	Ductility, Percent Elongation in 50 mm
Stainless Steel, AISI 302, Annealed	7920	655	260	150	190	75	50

Table 3. Properties of Stainless Steel [5]

It can be seen from table 3 above that stainless steel is a very strong material and would be appropriate to use for cutting the tablet since it will be able to transfer enough force to cut the tablet in half.

Two different pills were tested in the laboratory using a Tinius Olsen machine for the force needed to cut the pills in half using a stainless steel razorblade. The two different pills that were tested were One-A-Day Women's Formula from Bayer Corporation and Move Free Joint Strengthener from Schiff Products. Table 4 shows the forces needed to cut the pills along with the initial and final weights of the pills to test the accuracy of the cut. Table 5 shows how the velocity of the blade affects the force needed to cut the tablet as well as the accuracy using the percent change in weight.

Pill Force Testing						
	Trial #	Speed (in/min)	Maximum Force (lbs.)	Initial Weight (g)	Final Weight (g)	% Change in Weight
Move Free: Joint Strength	1	0.1	2.60	1.74	1.70	2.13
	2	0.1	3.40	1.74	1.64	5.75
	3	0.1	3.40	1.74	1.63	6.32
	4	0.1	3.40	1.74	1.68	3.45
	5	0.1	2.60	1.74	1.63	6.32
	Average	0.1	3.08	1.74	1.66	4.79
One a Day: Women's	1	0.1	2.60	1.76	1.66	5.41
	2	0.1	3.00	1.76	1.65	5.98
	3	0.1	3.00	1.76	1.70	3.13
	4	0.1	3.00	1.76	1.62	7.69
	5	0.1	2.20	1.76	1.60	8.83
	Average	0.1	2.76	1.76	1.65	6.21

Table 4. Pill Force Testing

Pill Velocity Testing						
	Trial #	Speed (in/min)	Maximum Force (lbs.)	Initial Weight (g)	Final Weight (g)	% Change in Weight
One a Day: Women's	1	0.10	3.40	1.76	1.66	5.51
	2	0.10	4.30	1.76	1.65	6.25
	3	0.10	4.00	1.76	1.66	5.97
	Average	0.10	3.90	1.76	1.66	5.91
	1	0.50	3.70	1.76	1.69	3.98
	2	0.50	3.40	1.76	1.69	3.98
	3	0.50	4.00	1.76	1.71	2.84
	Average	0.50	3.70	1.76	1.70	3.60
	1	10.00	3.40	1.76	1.71	2.84
	2	10.00	3.00	1.76	1.70	3.41
	3	10.00	3.00	1.76	1.74	1.14
	Average	10.00	3.13	1.76	1.72	2.46
	1	20.00	2.20	1.76	1.74	1.14
	2	20.00	1.90	1.76	1.71	2.84
	3	20.00	2.00	1.76	1.76	0.00
	Average	20.00	2.03	1.76	1.74	1.33

Table 5. Pill Velocity Testing

Table 6 shows the maximum force and change in weight corresponding to different blade speeds.

Speed (in/min)	Maximum Force (lbs.)	% Change in Weight
0.1	3.9	5.91
0.5	3.7	3.6
10	3.13	2.46
20	2.03	1.33

Table 6. Speed, Maximum Force and Percent Change in Weight

Figures 7 and 8 show the relationship between blade speed and maximum force and blade speed and accuracy, respectively.

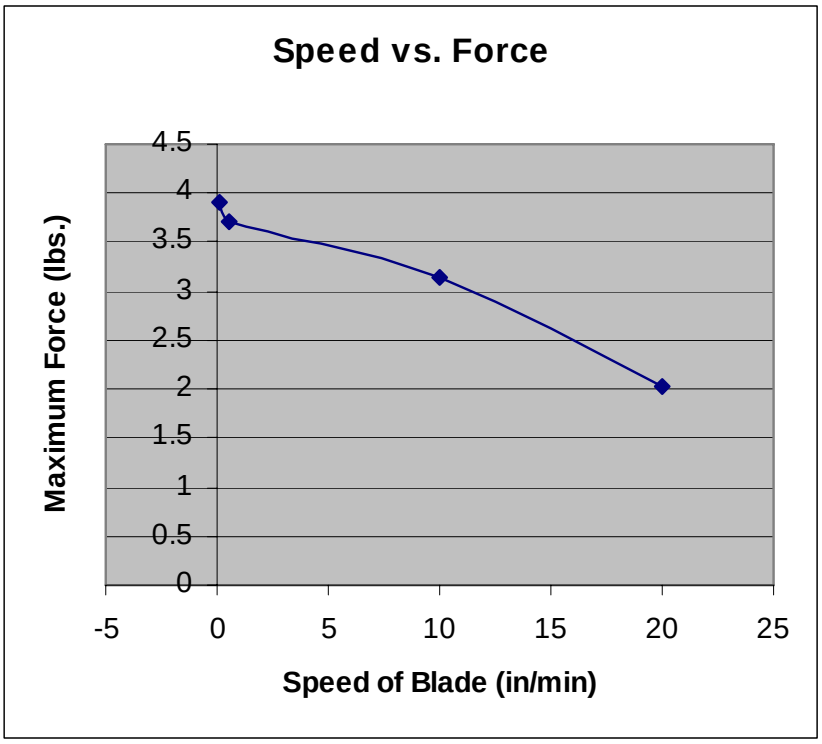


Figure 7. Speed vs. Force

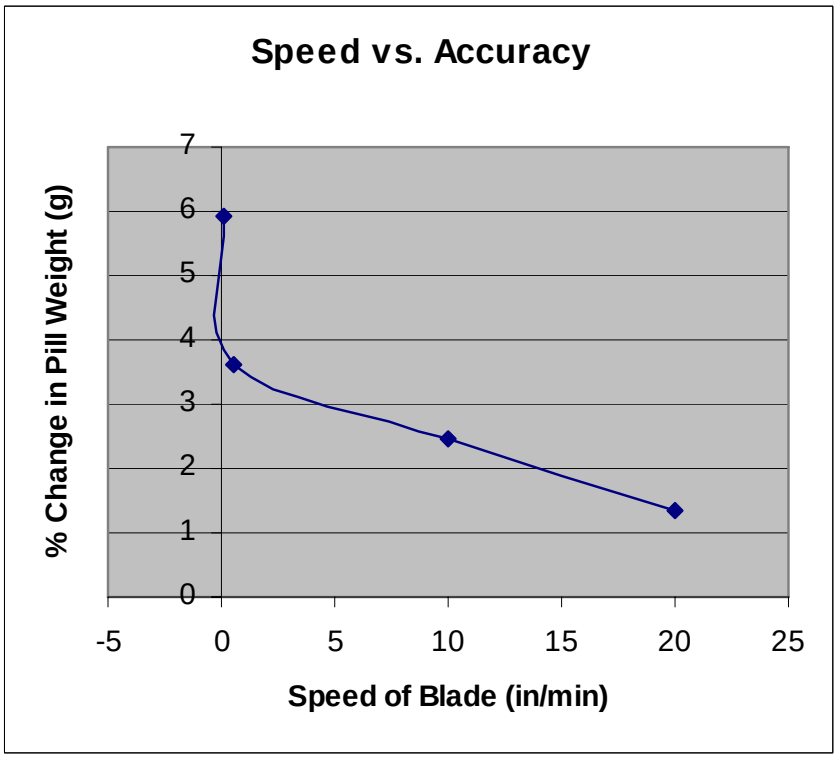


Figure 8. Speed vs. Accuracy

Using this data, an appropriate motor can be selected to cut the tablets in half. The stainless steel blade will be welded onto the end of the linear actuator motor. The maximum force measured that was needed to cut the pills was 3.9 lbs (17.35 Newtons) which corresponds to a very small blade speed. An ideal blade speed would be above 20 in/min since less force is required with this speed, and the accuracy increases. It is clearly seen from Figures 2 and 3 that as the blade speed increases, accuracy increases (percent change in weight decreases) and required maximum force decreases. A faster motor is also desirable so the patient's wait time for a pill to be dispensed is decreased. A small but powerful linear actuator motor with a speed of greater than 20 in/min like the Danaher Motion Digital Linear Actuator 42DBL20C2B-L will be used. This motor has a diameter of 42 mm and consumes 10 watts of power. The maximum force applied is 16.25 lbs (72.28 Newtons) and maximum travel distance is 2.4 inches (0.061 meters) with a maximum speed of 36 in/min. An image of this motor can be seen in the following figure, Figure 9. [6]

Figure 9. Danaher Motion Digital Linear Actuator 42DBL20C2B-L

The MEDSense pill dispenser will use the basic concept of gravity to dispense the tablets. When the alarms alert the user that it is time to take their medication, the user will invert the system so the pill cap is towards the ground. The pills will flow through a funnel just below the pill bottle. At the bottom of the funnel, a chute will be present with a width just large enough for one pill to fit through. One pill will move through the funnel and down the chute. The size of the funnel will depend on the type of pill being dispensed, so this device will be pill-dependent. There will be a different size device for the different size tablets used. The pill will be stopped by a sliding door below the chute so exactly half the pill is exposed out of the chute. The pill will then be stabilized in the chute. Another sliding door will close above the pill inside the chute. The cutting blade will come from one side and cut the pill in half. The bottom sliding door will then open and release the half pill to the patient. When the next half pill is needed, the blade will retract and the other half of a pill will be released to the patient. If a whole pill is needed, the blade will not move and an entire pill will be released to the user. A sensor will be used under the chute to ensure that the pill is in the correct position and ready to be cut. In the case of a jam or that the pill is not in the correct position, the sensor will send a signal to an LED alert which will warn patients that the pill cannot be cut. If this is the case, the patients will be told to re-invert the device so the pills can be re-aligned in the chute. A diagram of this process can be seen below in Figure 10.

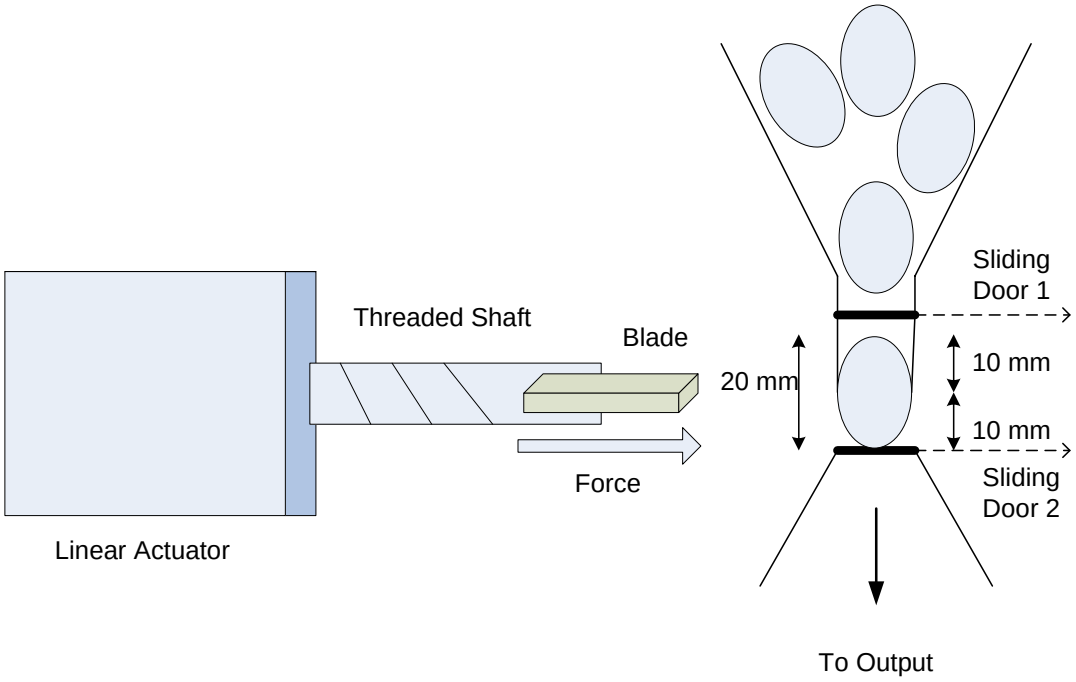


Figure 10. Cutting Mechanism.

This design can be used to dispense ½, 1 or 1 ½ pills. The following figure, Figure 6, is a flowchart describing the cutting process the MEDSense dispenser goes through in order to release these three amounts of medication. In order to dispense 1 ½ pills, first one pill will be dispensed then a half pill. At the next medication time, first a half pill will be dispensed then one pill using the same process described below.

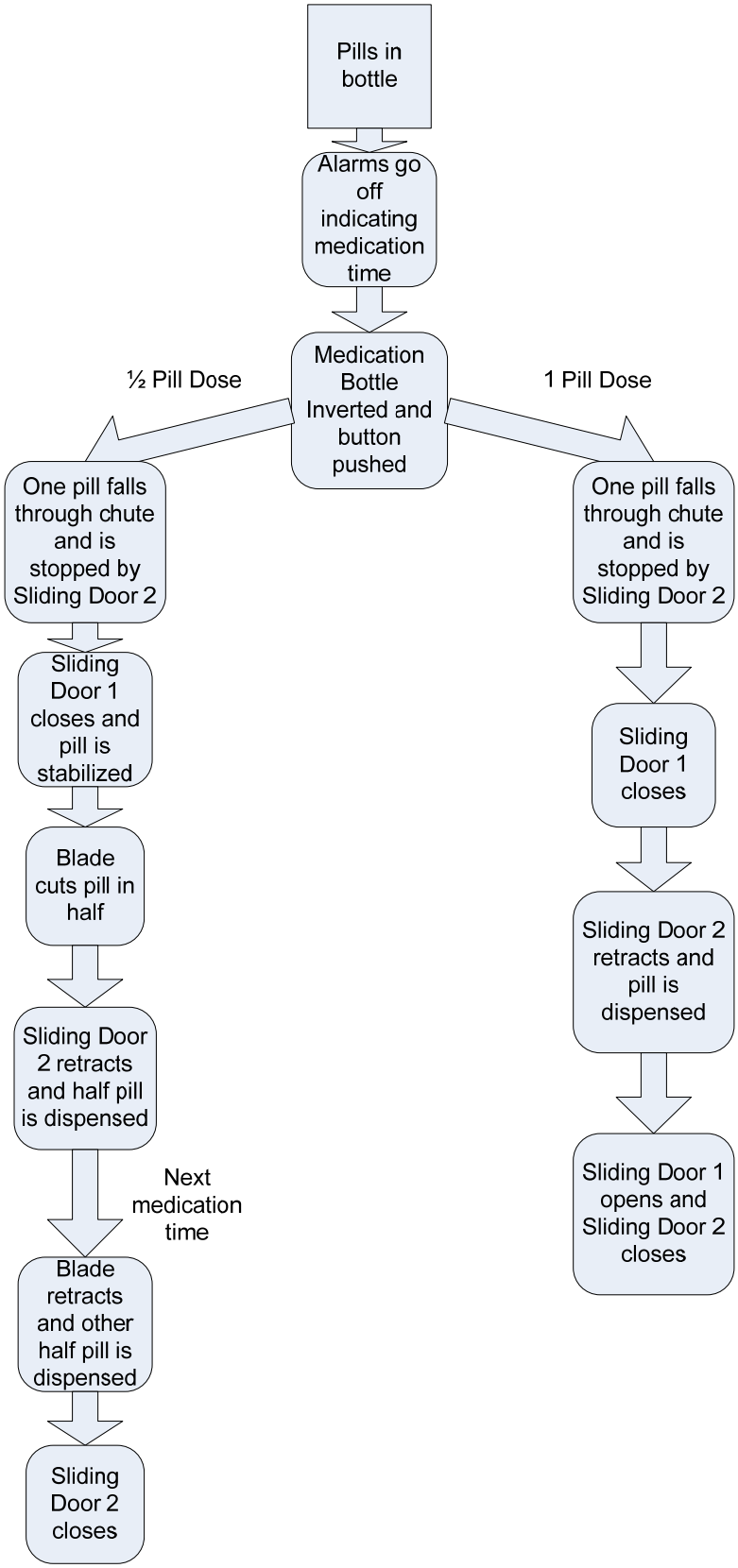

Pills in bottle
Alarms go off indicating medication time
Medication Bottle Inverted and button pushed
½ Pill Dose
1 Pill Dose
One pill falls through chute and is stopped by Sliding Door 2
Sliding Door 1 closes and pill is stabilized
Blade cuts pill in half
Sliding Door 2 retracts and half pill is dispensed
Next medication time
Blade retracts and other half pill is dispensed
Sliding Door 2 closes
One pill falls through chute and is stopped by Sliding Door 2
Sliding Door 1 closes
Sliding Door 2 retracts and pill is dispensed
Sliding Door 1 opens and Sliding Door 2 closes

Figure 11. Cutting Mechanism Flowchart

The motors that will be used to control the two sliding doors will also be linear actuator motors but only have to produce enough force to open and shut the doors. Therefore, very small motors can be used, such as the Danaher Motion Digital Linear Actuator 20DAM40D1U-K. This motor is only 20 mm wide, consumes 5 Watts of power, and produces a maximum force of 1.88 lbs (8.34 Newtons). All the motors used in this device will be controlled by the microprocessor. A picture of this small linear actuator can be seen in Figure 12. [6]

Figure 12. Danaher Motion Digital Linear Actuator 20DAM40D1U-K

iii. Notification System

It is necessary that the pill dispensing device has a mean of notifying users of various points of interest. To address the needs of a universal audience, the notification systems must stimulate multiple senses. MEDSense will feature visual alarm systems to accommodate users that are hard of hearing and auditory systems to accommodate users that are blind. Additionally, the device will vibrate when there is a notification to ensure that patience with both poor eyesight and hearing are clearly informed. Most importantly, the device will notify the user of when to take their medications. A microprocessor will be programmed with various command strings that remind the user to take their medications at certain time intervals. These strings will be input to a text to speech module that will verbalize the command. Selected times will be specific intervals before medication is dispensed, as selected by the user. The user can, for example, select that the device notify him/her every ten minutes before pills are dispensed to ensure that they are nearby and able to take their medications at that time. For a user with a busier schedule, selecting that the device notifies him/her half an hour before dispensing medications could be more convenient. Additionally, the user can select that the device notify him/her multiple times before dispensing pills. When the medications are dispensed, an alarm will sound and the "release" button will flash. Once the release button is pressed and pills are dispensed, a voice command will notify the user of consumption parameters specifying what medium to take with the pills (i.e. take with food, take with water, etc.). There will also be a volume control to ensure that all users are clearly notified.

In order to accomplish speech capabilities, the device will be installed with an IC2 text to speech synthesizer, a Devantech product distributed by Acroname Robotics. This compact module is 1.57 inches in length in 1.57 inches wide making it more than acceptable in size for the estimated design. The device runs on a 5V power source with a tolerance of approximately 10 percent. The standby current required is 20mA and the active speech current is 80mA. Additionally the device features an audio amplifier, an imbedded PIC processor, a Winbond WTS701 speech chip, and a 40mm speaker. The speech module has the ability to repeat 30 different text strings, each containing a maximum of 81 characters. A total of 1925 characters can be programmed. Although

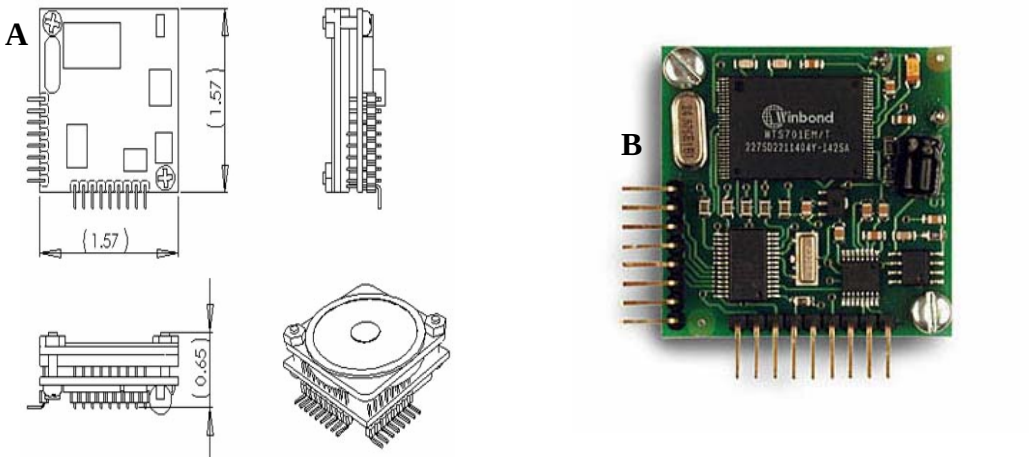


Figure 13. A look at the IC2 text to speech synthesizer. A) Schematic drawing B) Top view

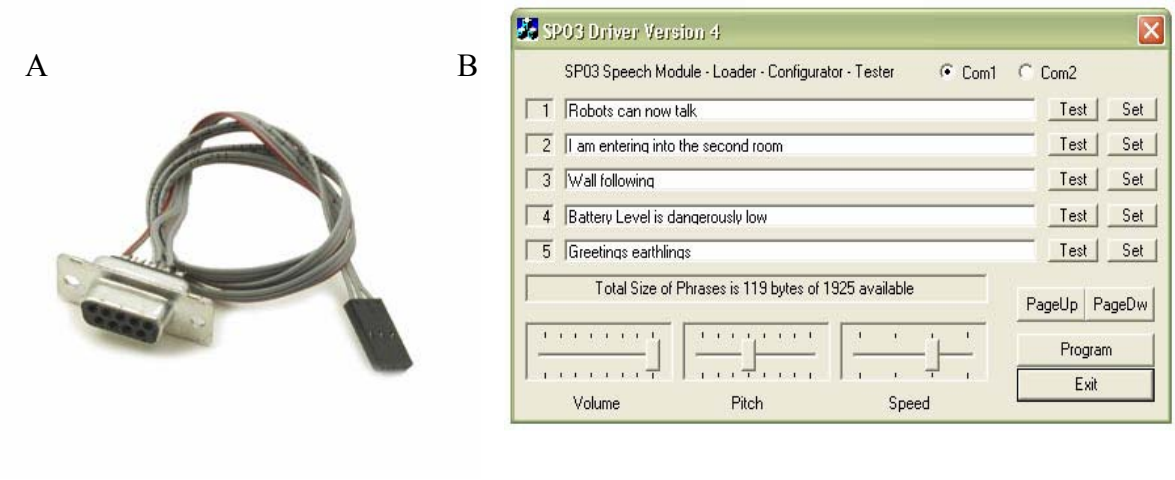


Figure 14. SP03 Programming. A) RS232 serial cable B) SP03 interface

there are 30 predefined phrases available that are automatically programmed into the module, the user has the option of programming personalized text strings [7]. This can be accomplished by programming the device SP03 module using the Brainstem Console Program, which is downloaded for free from acroname.com. Once the programming is established, the computer can communicate to the speech synthesizer using a standard RS232 serial port that will connect to the GND, RX and TX pins on the SP03 chip embedded on the device. Once the speech module is implemented into the pill dispensing device, it will be programmed to initiate specific text strings at programmed time intervals.

Visual notification systems will include a series of LEDs that will notify different occurrences. A static red LED will indicate that medications are not to be taken. When there is no action or response required (ie not prescribed medication time) the red LED will be constantly on. When there is a response required from the user a green blinking LED will be triggered and will continue to trigger until the user responds. At medication time, for example, the green LED will be blinking, notifying the user to press the pill release button on the side of the device. When the button is pressed, the blinking LED will no longer blink and the pill will be dispensed. The triggering of these LEDs will be programmed into the microprocessor.

Additional visual notifications will include a PC mount LED array that will act as a low battery indicator. A full battery charge will show all bars illuminated with one bar deactivating as the battery loses its charge. The LED array will feature a total of ten illuminating bars, thus, each bar will represent 10 percent of the total charge. As a device that relies heavily on the ability to keep time, a loss of power by depleted battery charge could lead to a loss of exact regulation of prescription times. A battery level indicator will clearly notify users of when to change the batteries in their MEDSense unit.

The trigger switch that will ultimately release pills will also feature a visual notification. By using an LED pushbutton switch from Honeywell, the user will be clearly notified of what action to take when it is time to dispense pills. The switch will feature pushbuttons,

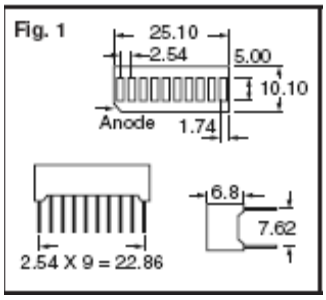


Figure 15. A) LED array
B) Push Button

paddles, rockers, solid state indicators as well as electronic key locks with LED, incandescent and neon illumination.

While creating the auditory and visual notification systems are relatively straightforward, notifying the user through their sense of touch proves to be a more difficult task. Similar to the E-Pill vibrating reminder device, the MEDSense will feature a vibrational device that will trigger at programmed medication times. Although there are many vibration sensing devices available on the market, there are no readily available devices that cause a device to vibrate. As a result, the MEDSense will feature a homemade vibration system.

A simple rotational dc motor will be stabilized in a sturdy plastic container. Attached orthogonally to the rotational end of the motor will be a small plastic gear that will rotate clockwise when the motor is activated. Attached parallel on the perimeter of the plastic gear will be a small weight. Due to the rapid rotation (100 to 150 RPM) of the system, the rotating weight will rapidly change the center of mass of the system causing a "wobbling" motion. As the speed of the motor increases, the wobbling will increase until it is a quick vibrating response [8]. The homemade vibration device will undoubtedly require a significant amount of trial and error and trouble shooting. As a result, precise values have not yet been determined. However, the basic design has been clearly conceptualized.

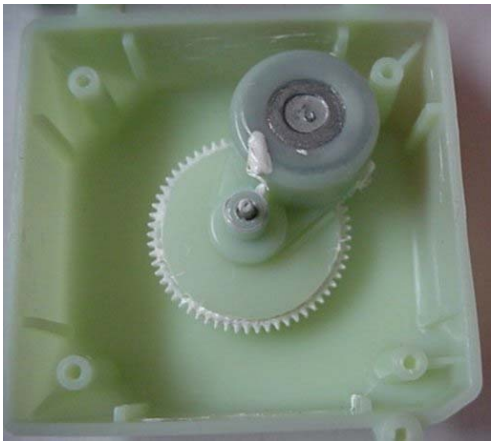


Figure 16. Similar vibration system [6]

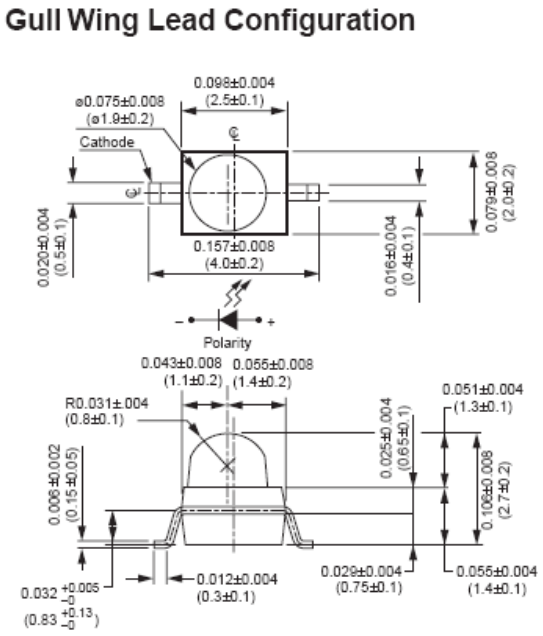
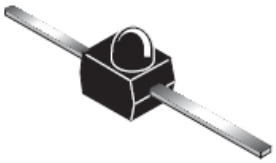


Figure 17 Photodetector Diode

Additionally, it is important to have a failsafe notification in the event that there is a jam in the pill dispenser. Although the funnel device described in previous sections is the most efficient method to ensure that only one pill passes through the system at a time, there is a slight possibility that the device jam at the funnel output due to the random orientation of pills. A simple optical system will be installed at the funnel output to detect a jam in the pill dispensing funnel. At the second trap door where the pill will rest vertically before being cut, there will be a simple photodiode LED on one side of the pill and a photodetector on the other. The photodetector diode used will be a QSB363 Subminiature Plastic Silicon Indrared Phototransistor from Fairchild Semiconductors. When there is a pill resting vertically, the path of the photons will be blocked and the cutting and dispensing process will continue as programmed in the PIC microprocessor. When there is no pill however, the photodetector will be excited and the process will not continue. This case will suggest that there is no pill in place due to a jam in the funnel. The photodiode and the photodetector will be activated when the user presses the "pill dispense" button described in previous sections. The optical system will be programmed into the same PIC microprocessor that controls the entire system as an "If, Then" type program. *IF* the photodetector is not excited, for example, *THEN* system will continue to function as programmed. On the other hand, *IF* the photodetector is excited, *THEN* the microprocessor will activate a notification LED on the external shell of the device. The external LED will signify to the user that they need to shake the device. The "shaking" or "vibrational" motion will immediately reorient the pills in the reservoir in such a way that one will fall through the funnel exit. Rough simulations of the effects of this motion on a jammed funnel have been performed using One a Day: Women's vitamin pills and a simple plastic funnel. Due to the random orientation of the pills in the static reservoir, it is likely that there will be a jam blocking any pills from exiting the funnel to be cut. From the rough experiment performed, however, even the slightest amount of motion is sufficient to reorient the pills, making it very unlikely that the user will need to apply a significant amount of energy or force to shake the device.



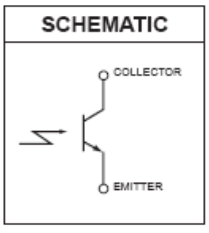


Fig 18 Photodetector and Schematic

iv. Offsite Alert

Not until now has the technology been readily available to allow a small pill dispensing device to communicate wirelessly to an emergency contact. Therefore, the ability of MEDSense to use Bluetooth technology to immediately contact a third party member when medications are not taken correctly or when the device is tampered with will be a hallmark of this design. From the pharmacist interface any phone number can be programmed into the device allowing a wide variety of users to take advantage of the offsite alert feature. While elderly individuals might choose to have the device call their doctor or pharmacist, a busy mother could have the system call her own cell phone as a double reminder in case the notification systems do not successfully catch her attention. Additionally, rehabilitation patients using the MEDSense device as a means of strictly regulating their medication intake to avoid a relapse of chemical dependencies could program their rehab officer's contact information into the device to notify them of when medications are not taken correctly or if the device is tampered with. It is crucial for the safety of the patient to take their medication on time, and the offsite alert is a failsafe system to maximize the safety and health of the patient. If they miss a dose, the third party member is alerted and can respond however they feel fit. The MEDSense dispenser will be a wireless device using Bluetooth technology. There will be a Bluetooth module in the dispenser that will send a short-range signal with a frequency in the 2.4 GHz spectrum to a nearby computer with Bluetooth technology that is also connected to the internet. The computer will in turn send a text message to a pre-programmed cell phone number of the assigned caretaker. This cell phone number will be programmed into the MEDSense dispenser with the other information. The device will send an alert offsite if the dose is not taken within thirty minutes of the start of the alarm. Therefore, if the button to dispense medication is not pushed within thirty minutes of the programmed dosage time, the caretaker will be alerted through a text message and be able to come to the aid of the patient.

The specific device that will be built into the MEDSense system is an RCM3100, EmbeddedBlue eb506-AHC-IN Bluetooth Radio Module from A7 Engineering and distributed by Rabbit Semiconductors. With advances in technology, many of the tedious programming requirements are no longer need because the devices come pre-programmed. This particular model features fully implemented components on the board to ensure that no additional code is required. Additionally, the embedded UART interface will automatically search, connect, and communicate with other Bluetooth devices nearby. Once it is located, connection to another Bluetooth device is designed to mimic the appearance of a serial connection so that users do not need to have a full knowledge of wireless communication protocol. The rabbit Bluetooth module also requires a low driving

Figure 19 A7 Engineering Blutooth Kit

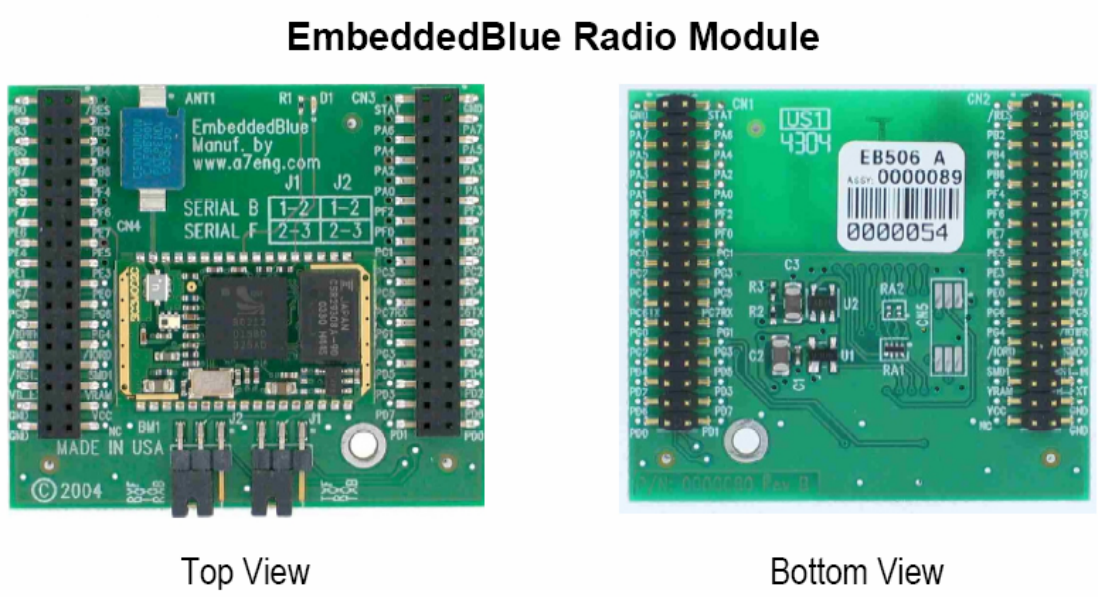


Fig 20. Embedded Blue Radio Module. A) Top View B) Bottom View

current, which should ultimately prolong the system's battery life. A standby current of 3mA and a data transfer current of 25mA is required. The driving voltage is also low at a value of only 3.3 Vdc. The Bluetooth module will be purchased as part of a kit including RCM3100, EmbeddedBlue eb506-AHC-IN Bluetooth Radio Module, prototyping board, and miscellaneous cables and hardware. Although it is not absolutely essential to purchase the entire kit, it would undoubtedly be useful to have the informational resources that are included. This will ensure that even with a limited knowledge of wireless transmission and programming, the device will successfully be integrated into the final system with optimal efficiency. Also included are the Dynamic C Integrated Development Environment, Bluetooth drivers, libraries, sample programs, and manuals. The sample programs and manuals should prove to be an integral element to the programming and integration of the Bluetooth device into the system. The communication device will be activated by a programmed microprocessor.

v. Pharmacist Interface

The original idea once the group received the product description was to have the user program the device. The user interface would have been easy to use and clear to those persons who have disabilities. Upon further review, the group realized this idea was impractical. Those persons with vision or motor loss would have difficulty programming any device regardless of the simplicity seen by the designers. Furthermore, these users would have to learn new technology which could be very intimidating. Also, from a design standpoint, many safeguards against incorrect programming would have to be instituted. The process of instituting numerous safeguards would be cumbersome and add complexity to the programming of the device. Even if these safeguards were a part of the device, there would still be a substantial risk that the device would be programmed incorrectly. This could cause either too much or too little medication to be dispensed

which could have grave consequences. Another factor to take into account with the user programming method is that people could become discouraged. If the programming proved to be too difficult or the device too complicated people would not use the device and thus the device would not provide a service. All of these problems could easily be solved if the user was taken completely out of the programming aspect of the design. This particular design reflects this ideal.

Instead of the user programming the device, the pharmacist will program this device. There are many reasons for this. The first reason is that the product would be sold to the pharmacist instead of the user. The pharmacist would then give the device to the user along with the medication which allows for preprogramming. More products could be sold if the device were sold to a pharmacy instead of the actual users. Another reason is that the pharmacist, in theory, would better be able to program a device than a person with various disabilities. If the device were to be sold on the market a company could send representatives to the pharmacist for extensive training which would ensure that the pharmacist was comfortable with the program. After this training, the pharmacist would be able to correctly program the device with ease. The final reason for the pharmacist to program the device is that the pharmacist would know the correct dosages for the medication. This eliminates the possibility that the user could enter the wrong amounts of medication due to vision impairment or simply misreading the label.

Though having the pharmacist program the device is better than the user programming method, it is not without limitations. Most pharmacists would not have extensive experience in computer programming. If the interface was too difficult to understand for the pharmacist, the pharmacist would not use the product. The legal ramifications for programming the device incorrectly would be too great for the pharmacist to undertake. In some instances the pharmacist could be held liable if a person took the wrong amount of medication due to incorrect programming. Therefore, the first element of the pharmacist interface must be clear and easy to use. The second limitation of having the pharmacist program the device is the lack of resources in a pharmacy. A pharmacy is unlikely to have complex equipment to program microprocessors. Due to this fact, the device must be able to be programmed by a personal computer. This design aims to solve both of these potential problems

Figure 21 shows the design of the pharmacist interface. The group chose National Instruments LabVIEW to create the pharmacist interface. LabVIEW has the capability to create clear interfaces as well as program microprocessors which will be used in this device. Note the clarity of the design as well as instructions above the fields. A detailed explanation of these fields will follow within this section.

The first field to be discussed is the "# of pills per dose." The field is a numeric control which allows for the user to input the desired amount of medication. The default amount for the field is zero. A default amount of zero requires the pharmacist to actively implement the dosage which reduces mistakes. Numeric controls allow the user to easily input the desired amount by simply typing in the amount or using the up or down arrows to either increase or decrease the value. Within this numeric control the pharmacist will

enter the dosage amount. The value in this field will tell the device the correct amount of medication to be dispensed at the determined times. Numeric controls allow for the input of fractional amounts. Fractional amounts will alert the device to dispense half pills after being cut by the mechanical elements. In the previous design a cut pills trigger was included. This was excluded from this design because it is redundant because the device could determine if the pills should be cut from the fractional amount entered. The cut pills button was entered as a safety factor but the function it would provide would not be worth an extra step for the pharmacist.

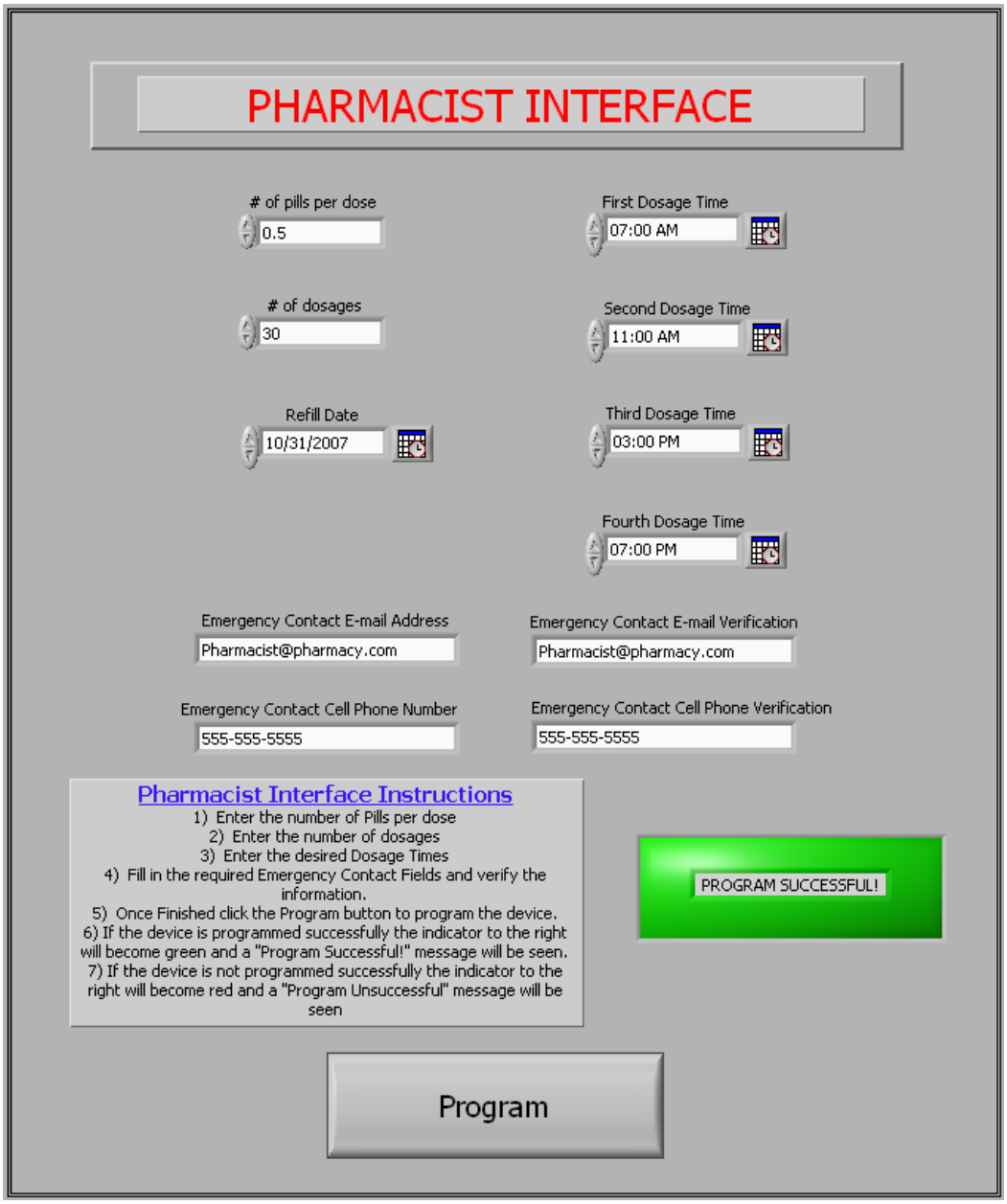

PHARMACIST INTERFACE
# of pills per dose
0.5
# of dosages
30
Refill Date
10/31/2007
First Dosage Time
07:00 AM
Second Dosage Time
11:00 AM
Third Dosage Time
03:00 PM
Fourth Dosage Time
07:00 PM
Emergency Contact E-mail Address
Pharmacist@pharmacy.com
Emergency Contact E-mail Verification
Pharmacist@pharmacy.com
Emergency Contact Cell Phone Number
555-555-5555
Emergency Contact Cell Phone Verification
555-555-5555
Pharmacist Interface Instructions
1) Enter the number of Pills per dose
2) Enter the number of dosages
3) Enter the desired Dosage Times
4) Fill in the required Emergency Contact Fields and verify the information.
5) Once Finished click the Program button to program the device.
6) If the device is programmed successfully the indicator to the right will become green and a "Program Successful!" message will be seen.
7) If the device is not programmed successfully the indicator to the right will become red and a "Program Unsuccessful" message will be seen
PROGRAM SUCCESSFUL!
Program

Figure 21 Pharmacist Interface Design

The field below the first field is the "# of dosages" field. This is another numeric control with the same properties as the "# of pills per dose" numeric control. Once a value is entered into this field it will allow the device to know exactly how much medication is in the device. After each medication is dispensed the device will update the amount of medication in the device. Once the medication is low, there will be an alert to the user that the medication needs to be refilled. This will allow the user to plan a trip to the pharmacy days in advance.

Below the "# of dosages" field is the expiration date. This is a time stamp that only includes the date instead of the time. Knowing the expiration date of the medication will allow the device to notify the pharmacy as to when the prescription needs to be refilled. This will allow the device to alert the pharmacy so that when the user goes to the pharmacy the prescription will be ready for them.

On the right side of the interface is a series of dosage time fields. To set times within a LabVIEW program time stamps are used. The default settings for the time stamp include the date as well. Note that the date is not seen in any of the time stamps in Fig. 21. Since programming the date of each dose is unnecessary it was removed so it would not confuse the pharmacist who may think the date is necessary. Within the properties of the time stamp the date can be removed. The default value of the time stamp is 00:00 PM. Pharmacists can change the value in these areas by either typing in a new time or by using the arrows to either increase or decrease the time within the field. It is the hope of the designers that the pharmacist could work in accordance with the user to program the times that would fit the user's schedule. This provides the user some control over the times to take the medication without the potential hazards of programming. For display purposes, this interface was designed for a medication that needs to be taken four times per day. The final interface would allow for the pharmacist to input the number of dosage times needed. This increases the versatility of the program in accommodating many different medications.

Towards the bottom of the interface is the emergency contact information. This is one of the unique features of this device. One major element of the device is its ability to notify someone offsite if a person does not take their medication. A person offsite could check up on the user and make sure that there are no problems with either the person or the medication. This could be especially useful in elderly users who consistently have family members monitor them. Another usage of the offsite alert would be to allow living assistants or nurses to know what medication has not been taken. This design does not have a tolerance feature for missed medication right now. The reason for this is that it would be difficult for a pharmacist or doctor to figure out the amount of medication that could be missed without effects due to the fact that medication affects people differently. While it could be unnecessary to notify if certain medications are missed once in awhile, it is better to err on the side of caution.

LabVIEW has the ability to send text messages to PDAs. This would allow instant contact to family, medical professionals or persons taking care of the user. Each cell phone acts as an e-mail address for receiving messages. Text messages can be sent from a computer to a phone or a phone to a computer. Knowing that cell phones in essence have e-mail addresses, the device will also send an e-mail. If a person does not have text receiving capability or is not with their phone, there will be a second level of notification. This second notification is by e-mail. The device will send a short message to an e-mail address saying that the person did not receive their medication. By inputting these values as strings, the pharmacist will provide information as to how to contact important people. The numbers and e-mail addresses will be provided by the user which again allows the user increased control over their health.

Verification is another important element of the pharmacist interface. The offsite notification will not work if the entries provided by the pharmacist were incorrect. By asking the pharmacist to input the values twice it decreases the risk since it unlikely the person would make the same mistake twice. The program would compare the two string values. If the string values are not the same in both the e-mail and phone number fields, an error message will be displayed. The only way the device can be programmed to have invalid offsite alert strings is that the pharmacist makes the same mistake in entering the values twice.

Directly above the program button is detailed instructions as to how to operate the pharmacists interface. This should greatly reduce any confusion as to how to program the device. Instructions are provided on the interface to ensure that everything is done correctly as well as to save time. It would take a lot of time to refer to a user's manual to solve programming problems. Reducing the time it takes to program the device would make the device more attractive in the market.

The final element of the pharmacist interface is the "Program" button. Once the "Program" button is pushed, the program will check all fields for the correct information. This design has both a light and a text indicator of the result of the programming. If the device is programmed successfully the light will become green and a message reading "Program Successful!" will be displayed. If there are errors within the fields the device will not be programmed, the light will become red and a message reading "Program Unsuccessful" will be displayed. Adding text to the changing color provides another level of notification. This is much clearer than the previous design where only a color indicator was present.

If all values are inputted correctly, the computer will begin to program the device. This particular design calls for a DB9 serial (RS232) connection. Most pharmacies use desktop computers which have this type of connection. The DB9 serial connection has a few distinct advantages. The first advantage is that the group has worked with using DB9 serial connectors in previous projects. This understanding of how this connection works would ease in designing a program for the device. If the group used a USB connection the group would have to learn a new connection method and new technology. Another advantage is that the pin out diagram for the DB9 serial connection is easily found. This

will allow easy attachments during the production phase of the project. While a USB connection may be easier to use, the DB9 would not add a considerable amount of difficulty in attaching the device to a computer.

National Instruments LabVIEW has an application called VISA that can interact with a DB9 connector. This application would allow the group to use LabVIEW, the program on which the interface is written on, to also pass information to the device. In past projects the group has seen the interaction between the DB9 serial connector and a microprocessor so programming a microprocessor using LabVIEW and a DB9 serial connection will be possible.

III. Realistic Constraints

i. Engineering Standards

The FDA classifies medical devices into three categories. Class I devices pose little risk to the patient. If a device fails it will have a minimal adverse affect on the patient. Class II devices are more risky to the patient when failure occurs but are not used to sustain life. Class III devices are life sustaining devices. This design would be of a Class I device because if the device were to fail it would not directly affect the health of the person. It could potentially make the process of obtaining medication more difficult but it would not injure the person [9].

For production the manufacturer of the device would have to register with the FDA. This process is done by an online application. Following registration the manufacture would have to list the devices produced with the FDA. Class I devices are exempt from the Premarket Notification and Premarket Approval sections because of the low risk involved. This device would be subjected to Good Manufacturing Practices (GMP) and Quality System (QS) Regulation. The GMP/QS regulations ensure that medical devices are safe to use by consumers. The higher the risk posed to patients by the device, the higher the scrutiny of the review. Table 1.1 shows the list of requirements by the GMP/QS [10]. Once all these requirements were satisfied to the FDA standards the device could be sold in the United States.

1. Obtaining information on GMP requirements
2. Determining the appropriate quality system needed to control the design, production and distribution of the proposed device
3. Designing products and processes
4. Training employees
5. Acquiring adequate facilities
6. Purchasing and installing processing equipment
7. Drafting the device master record
8. Noting how to change the device master records
9. Procuring components and materials
10. Producing devices
11. Labeling devices
12. Evaluating finished devices
13. Packaging devices
14. Distributing devices
15. Processing complaints and analyzing service and repair data
16. Servicing devices
17. Auditing and correcting deficiencies in the quality system
18. Preparing for an FDA inspection

Table 7- GMP/QS requirements [10]

ii. Economics

A major problem with an entirely disposable device is that the electronic components can be very expensive. The group entertained the idea of a fully disposable device due to its high versatility in the sense that each device could be made for only one pill size and shape and the potential to sell many units due to the high number of prescriptions taken each year. The major problem with the disposable device is that the cost would be very high and thus not attractive to pharmacies who desire to keep costs low. A way to keep the versatility and high marketing potential of the disposable device while making it a wise investment for pharmacies is to make the device partly disposable.

A partly disposable device allows the electronic components of the device to be returned to the pharmacy after use while the mechanical part is disposed of. By creating a disposable mechanical part, each particular device needs to only accommodate one pill size and shape. The group can then design separate mechanical parts to accommodate different sizes and shapes. This allows for the company to make a profit on each prescription since a new mechanical part will need to be purchased. Another benefit of this design is that it can easily be used by all persons taking prescriptions. The vast majority of pills do not need to be cut. The pharmacist would only have to attach a mechanical part that dispenses pills but does not cut them. These people could take advantage of the alert systems but not have to pay for something they would not use such as the cutting device. Cost is still a major challenge with this device. The group must still make the mechanical part of the device at a reduced cost so it would be financially

feasible to purchase a disposable part. Also the electronic part of the design should not be financially hindering. While the pharmacy will get more of a return on their investment, they would not spend too large an amount of money on the device.

While designing a low cost, partly disposable device presents challenges, it also presents opportunities. One major opportunity is that many mechanical parts of the devices will be needed. People will need a new mechanical part every time they refill their medication. In 1999, according to the most recent census, approximately 2.974 billion prescriptions were sold in the United States [11]. Since both the population of the United States and the pharmaceutical industry have grown, this number is sure to be much higher today than that of only eight years ago. It can easily be seen that the market for this device is very large. Since the market is large, only a small profit needs to be turned on each individual device to make a large amount of money for the company. This allows the mechanics of the device to be sold at close to the cost of manufacturing which could make the device attractive in the market. This is a luxury that would not be available to a non-disposable design.

iii. Environmental

With continued concerns about global warming becoming more important in mainstream society, the environmental impact of devices is becoming more relevant. More and more consumers are looking to the long term impact of devices on the environment as selling points for certain equipment. If the impact on the environment of this device could be minimized, it could become more attractive in the market and thus sell better.

All materials used in the product must not have an adverse reaction to the environment that would contaminate the surrounding area. Since the materials used in this device must be inert, due to the fact these materials have to be in contact with medication, the group does not expect there to be any environmental issues. The main components of the device will either be metal or plastic which would not pose environmental problems. This device will be only partly disposable after use which presents more problems. First of all the device once discarded will take up space in a landfill. The device will be small however so the group does not believe that it will harm the environment more than any other discarded object. The group has investigated biodegradable materials but they do not have the desired strength or reactive properties needed by the design. Plastic will be used wherever possible due to its low weight and relative high durability.

A rechargeable battery will be used with this design so that both the user and the pharmacy can recharge the device. This eliminates the battery disposable problems seen in the first design. A reusable device is undoubtedly the most environmentally friendly device and a completely disposable device is the least environmentally friendly device. This device falls in the middle of the two. The impact on the environment should be minimal but there will be an impact nonetheless.

iv. Sustainability

Sustainability long term is only an issue with the electronic part of the device. Pharmacies will only dispense medication for at most one to three months. Since one prescription can only last for a relatively short period of time, the mechanical portion of the device would theoretically only have to work for one to three months. The mechanical components of the design will be chosen based on the thought that the device will work for much longer than three months. This will ensure that the best possible materials are chosen for this subunit since mechanical failure would result in the device being useless. The electronic components will be chosen based on the assumption that the pharmacy will continue to use the device for years.

Sustainability of the power source will be a very important issue. Currently the group is looking for ways to reduce the amount of power consumed by the device. Reducing the power consumed will increase the battery life. This would, in turn, allow for more portability for the device. Ideally the device would come equipped with a single battery that would only have to be recharged and not replaced. The group will test the device under maximum operating conditions to find the amount of power consumed by the device. If it is found that one rechargeable battery or multiple rechargeable batteries together could sustain the device for sufficient amounts of time to make the device portable, the user would not have to go through the hassle of changing batteries.

v. Manufacturability

Manufacturability is an issue in designing any device. The ultimate goal of the device is to be put on all prescription bottles. Since there are billions of prescriptions written every year the manufacturing process would have to be easy so many devices could be produced in a short period of time. Shape is one aspect of manufacturability that the group has considered. A shape that has many angles and details may be aesthetically pleasing but would be difficult to manufacture. The group has chosen easy to manufacture shapes since cost, not beauty, will be the main selling point of the design. Also the group plans to use parts from retailers. This would aid in the manufacturing because the company would not have to build its own parts. Finally, the group aims to design a device in which the assembly is easy. The electronics would be separated from the mechanical aspects of the device so that each could be assembled separately and then put together. This would reduce the time of manufacturing since people would not have to wait until the electronic components to be assembled to assemble the mechanical components.

vi. Ethical

Profit versus quality is the major ethical question facing all companies. This question is easily answered because this is a medical device. Quality must be the first consideration. The group will design and build a device of the highest quality to greatly reduce the likelihood of failure. The device may cost more due to the increased quality but the potential consequences of building a low quality device are too great.

vii. Health and Safety

This device will have many safety factors to ensure that the device aids a person's health and does not hinder it. One safety factor is to only dispense medication at the desired time. This prevents people from overdosing on medication because they forgot how much medication to take. Another safety factor will be making the device childproof. The effects of medication on children are much more severe than adults. The portability of the device makes the device more childproof since the user can have the device close at hand at all times. Leaving the device at home with children while the user is away could result in the child taking the medication. People can bring this device with them and it won't be too large as to hinder their daily activities. Also, the user would have to actively push a button to receive their medication. This would prevent medication from being released when the person is not around. Safety in all conditions is also a consideration. The device will be waterproof since many people take their medication in the bathroom where water is present. Other safety factors include material selection and the alert system. The materials used in the device will not react with the medication. This is especially important in the blade being used to cut the pills. Any reaction could reduce the effectiveness of the medication or even cause harm to the user. All materials throughout the device will be inert. The alert system aims to notify users that have many disabilities. The multi-modal alert system will alert three different senses. The device will have visual, audio and vibrating alerts. This will allow persons with hearing loss, vision loss or both to be notified to take their medication.

viii. Social and Political

Many times persons with disabilities are not thought of in the design of devices. Countless devices cannot be used by persons with varying levels of disabilities because engineers did not take these individuals into account. This will not be an issue with this device. This device will allow persons with disabilities to have greater control over their lives which is what many of these people desire. Also it will allow these people to live healthier lives. The medications they are taking aim to increase the quality of their lives. This device aims to further increase that quality of life.

In the upcoming presidential election healthcare is undoubtedly going to be one of the most important issues each candidate will have to face. Some candidates have already proposed universal health care programs. This would provide health care to many more people in the United States. An increase in the amount of health care usually coincides with an increase in pharmaceuticals. As more people take medication, the impact of this device could greatly increase.

IV. Safety Issues

Safety is one of the biggest concerns in the design process of the MEDSense pill dispenser. Since the patients will have contact with this device multiple times per day, it is absolutely necessary that the device be perfectly safe for them to use. However, the safety of the patient is not the only concern. The design team must also think about the safety of other parties, such as children, and the environment. Different safety concerns that should be addressed by the design team are electrical, mechanical, chemical and environmental safety issues.

Electrical safety is one of the biggest problems for this device. It is a battery-powered device with many electrical components, including a microchip and two motors. A safe and fail-proof electrical circuit should be designed so that there will be no chance of this device shorting or overheating and injuring the patient. Correct soldering techniques, approved components and sufficient insulation are also required to ensure the safety of the user. A major issue with electrical safety is making the device waterproof. Almost all medications are taken with water so it is essential that the pill dispenser be waterproof. If the device was not waterproof, the patient could be seriously injured through electrocution, since water is a conductor of electricity, and the device could fail. The failure of this medication dispenser could be very dangerous for a user. Many of the patients will rely solely on this pill dispenser to keep track of their medication doses and schedule. If the device fails and does not remind a user to take their medicine, the patient could become very ill because of their missed dose.

The next big safety concern with this product is mechanical safety. The pill dispenser has the ability to cut pills in half, so will contain a sharp blade in order to cut the pills. This blade should be fully protected inside the device so there is no chance the user could harm themselves on it. There should also be no sharp edges or other sharp components present on which the patient could cut themselves, and the device should not be too heavy or bulky so the patient can easily manage it and not injure themselves while trying to use it.

Safety from chemical hazards is a large concern for the design of the pill dispenser. This device must be designed for use with many different medications which contain a variety of chemicals. The device must be designed with materials that are non-reactive to any chemicals present in the pills. The metal cutting blade should be non-corrosive and non-reactive when coming into contact with the medication, as well as the rest of the device. All of the materials used in the pill dispenser should be non-toxic and biocompatible since the materials will come into contact with an orally digested pill.

Perhaps the largest safety concern having to do with the medication itself is the risk of overdose for the patient or other persons coming into contact with the device. This pill dispenser should be completely childproof. Children often mistake medicine for candy and will swallow many pills at once. The device will be fully childproof, with the pills sealed using a childproof lock on the pill dispenser. Overdosing on medication is a serious health concern that should be fully prevented by the pill dispensing device. It will

be designed so the patient will only have access to the pills at the pre-programmed dosage times. This way, the risk of overdose for the patient is removed.

The last main safety concern for the MEDSense pill dispenser is environmental safety. Since batteries will be used in this device, the user should be instructed on how to safely dispose of them. The other components should be safely disposed of by the user. All the materials used should not be harmful to the environment when decomposing.

V. Global Impact

Having discussed both the demand for a portable device that cuts and dispenses pills and how MEDSense, specifically, will address these demands, it is important to extenuate the inevitable impact of such a device on the global community. Although its impact may take time to diffuse through the many facets of society, accurate speculations on the ultimate impact of the MEDSense device can be made for each individual facet including global, economic, environmental and societal context.

The primary impact of the MEDSense device is to improve and optimize the health of a global community. Individuals are becoming more and more dependent on prescribed medications, resulting in an increased need to remain organized and strictly methodical when consuming multiple daily medications. As a device that will automatically dispense correct medication dosages at the correct times, the ultimate impact of the device will be to significantly lower the possibility of misusing prescription drugs. Often times it is difficult for elderly individuals to sufficiently keep track of the correct dosages of medications and when to take them. Additionally, busy parents are often too involved with other activities to remember to take their own or their children's medications. Furthermore, parents with multiple children might find it difficult to organize and monitor multiple medications, dosages, and prescribed directions. As a solution, MEDSense will automatically notify the user of the medication times and dispense the correct dosage of pills, allowing the user to continue on with their regular busy schedules. By removing the human element, there is a much smaller margin of potential human error, resulting in an overall healthier global community.

Another global concern is whether or not some elderly individuals are capable of performing the required tasks to prepare each medication dosage and also take the pills in the correct prescribed manor. Not being able to correctly prepare dosages could lead to misuse or neglect of vital prescription medications. Many individuals, for example, are unable to divide single pills into halves for their correct dosages. Although the pills that need to be divided are often "perforated" at the break-point, many elderly men and women may be too weak or physically immobile to properly prepare their medications. In addition, they may be unable to remember or unable to read from the prescription label the proper way to take their medications. Some prescription drugs require that the user consume them with a specific fluid or perhaps with food. A simple antibiotic such as Tetracylclin, for example, must not be consumed with milk because the active ingredients

are deactivated by the Ca+ ions that are found in dairy products [12]. Not consuming the pills in the correct manor, therefore, could lead to unwanted and potentially fatal repercussions. As a solution, MEDSense will output a series of voice commands that will instruct the user of how to properly consume the specific pill to ensure that all users are safely following the suggested directions. These reminders will, as a result, significantly reduce the likelihood that an individual will misuse the prescribed medications, thus, improving the general health and safety of the community. As the presence of prescription medications available on the market increases, there is a concurrently increasing societal dependence on the consumption of pills. Many would argue that this increasing chemical dependency will ultimately have a negative effect on the overall health of the American public by artificially creating or altering chemical balances within the body. Medications like opioids, cns depressants, and powerful stimulants, for example, all have long term negative effects such as seizure, irregular body temperatures, cardiovascular failure, and even death in extreme cases [13]. A long term side-effect that is paralleled in many prescription medications is the strong possibility of creating a chemical dependency or an addiction to one in particular. When particular portions of the brain are stimulated by prescription medications, they deplete the brain's supply of dopamine, a chemical messenger that elicits feelings of "pleasure" throughout the day. With a lowered concentration of dopamine, patients will have reduced emotional reactions to daily activities. In order to reestablish a sense of feeling and enjoyment, the individual will turn to their prescription medication, which will force the excrement of dopamine. Without proper control of pill consumption regulation, many users of antidepressants and stimulants will deviate from their prescribed dosages, often consuming more pills than is necessary in order to feel good [14]. As a solution, the MEDSense pill dispensing device will be carefully programmed by a professional pharmacist to only dispense pills at the suggested times, eliminating the possibility of intentionally drug misuse. In fact, the MEDSense device could be specifically used on rehab patients that need strict regulation of their prescription medications. While assisted rehabilitation is an invaluable experience for those individuals in need of help with dangerous chemical dependencies, it is logistically impossible for there to always be a professional pharmacist or rehab officer sitting at their side to monitor their progress. MEDSense, however, could be used to automatically ensure the regulation of individual's pill consumption. Furthermore, the offsite alert will immediately notify rehabilitation professionals if the individual's medications are not taken on time or if the device is tampered with.

With a partially disposable instrument such as MEDSense, it is important to consider the potential environmental impact of the device. This design will feature inert, lightweight plastic materials for the majority of the parts. Inert materials will ensure that no detrimental environmental alterations will occur from the long term disposal of the device. Additionally, the possibility of using recyclable plastics is being researched, which would further minimize the environmental impact of the MEDSense pill dispenser. It should also be noted that it is important that users understand the proper disposal methods for used batteries. Properly disposing "empty" batteries will be clearly noted in the device instruction manual to ensure that there is a negligible amount of long term environmental impact.

One of the main deterrents of similar pill dispensing devices on the market is the incredibly high cost. Many devices cost anywhere between 800 and 1000 US dollars from retail outlets, a cost that most individuals cannot afford. The initial design of the MEDSense device, however, has an estimated budget of approximately 1000 dollars. Considering that the final product should cost about 35% of the prototype design, the final cost of the MEDSense pill dispenser will be a very manageable 300 dollars. This will allow individuals that are unable to afford other designs to purchase a pill dispensing device that will accurately manage their medications.

VI. Life Long Learning

This design project allows for enhanced education in the engineering discipline. This project allows for the development of new skills including design, budgeting and planning. As we go into industry, these skills will excel us so we can develop new and innovative solutions.

For the third design, the use of a motor device for cutting the pill has been suggested and the ability to remove half of the device. The advantages of using a motor device over a human mechanical device is that users with amputated arms, arthritis and other disabilities that limit human motor skills can use this device with ease. The previous designs call for the pill to be dropped on to the tablet plate or a disk but these designs had flaws. If the pill were to fall vertically and not horizontally, the pill would become lodged the wrong way, thus causing the device to become jammed. For this system, we will need to learn the properties of a linear motor, such as the amount of force the motor gives, so that the right amount of force will be used to cut the pill. The amount of energy that the motor needs to operate without exceeding certain restraints will need to be investigated. Also compression testing, on the medication itself, will need to be investigated; this will also help in determining the correct linear motor needed for this device. For the mechanical part of this design, many features will need to be investigated and thus life long learning will take place.

In order for this device to work properly, understanding the fundamentals of programming, timing, and design will be necessary. Because this design will have two sliding doors that act to keep out other pills and a motorized blade, it is necessary to gain the knowledge of timing and programming so that no two doors are open and allowing pills to fall through. The use of a scheduling system will be employed to alert the user when the medication is needed to be taken. Using LabVIEW, a program will be constructed so that the user's pharmacist will be able to set a correct schedule. For this it is necessary to learn the LabVIEW program and to develop a user interface that is easy for the pharmacist to use. Once understood this software will aid in the development of a scheduling system. Also, alerts will be used when the medication is needed to be taken and when the medication has not been taken. The software will help in the development of different alerts for the user.

For this third design, the skills that were learned are human mechanics and force needed to cut a pill in half, the LabVIEW software to build a scheduling system, and the alerts to notify the user when to take their medication. With all of these new skills, life long learning was applied. From working as a team to developing a pill dispenser, life long learning does not stop and these skills will help as we go into industry.

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